REMARKS

Claims 1-63 are pending in this application. Claim 1 is being amended to add the phrase "wherein under normal conditions of use more than 80% of the cefuroxime axetil is released in 4 hours and the outer coating does not enhance the rate of drug release from the composition." Support for this is found in the examples and in Figure 1.

The Examiner has rejected claims 1, 3-22 and 24-63 under 35 USC § 103 based on the cited prior art of WO 99/44614 and US 5,580,578. Applicants respectfully traverse this rejection.

The present invention is directed to a fast disintegrating controlled release form of cefuroxime axetil which provides for a stable controlled release so that the composition in normal use releases more than 80% of the cefuroxime axetil in 4 hours and the outer coating does not enhance the rate of drug release from the dosage form.

According to the Examiner, WO 99/44614 teaches:

1. Film coating techniques to mask bitter taste resulted in gelling of cefuroxime causing poor absorption of the drug.

2. Use in film coating of water soluble polymers could not completely prevent moisture absorption by cefuroxime axetil.

3. To remedy the above problem use of a micro-environmental pH adjuster and an anti-gelling agent around the compound in the form of silicon dioxide is proposed.

4. Eudragit L and Eudragit S are proposed as suitable polymers for film coating.

This publication does not disclose or suggest the need for a fast disintegrating controlled release oral composition having the properties of the composition claimed in this application.

According to the Examiner, US Patent 5,580,578 teaches:

Controlled release form having aqueous dispersion of hydrophobic aqueous polymer for taste masking, immediate release and stability over prolonged periods.

In addition, US patent 5,580,578 teaches that:

1. The aqueous dispersion proposed is plasticized pharmaceutically acceptable hydrophobic acrylic polymer cured at a temperature greater than the glass transition temperature of the aqueous dispersion of plasticized acrylic polymer to achieve a stable dissolution of the active agent which is unchanged after exposure to accelerated storage conditions. (See col. 3, lines 45-56).

2. Both pH dependent and pH independent polymer are proposed but essentially the coated substrate is cured to achieve desired stability.

As stated above, the present invention is directed to a fast disintegrating controlled release form of cefuroxime axetil which provides for a stable controlled release.

The formulation claimed in this application is a highly selective controlled release formulation of cefuroxime axetil comprising a core containing cefuroxime axetil as a controlled release form comprising (a) an outer coating of copolymer selected from aqueous dispersion of enteric methacrylic acid and methacrylic acid ester anionic copolymer having carboxylic group as the functional group or mixtures thereof and (b) an inner coating of sustained release copolymer selected from aqueous dispersion of acrylate and methacrylate pH independent, neutral copolymer having quaternary ammonium group as a functional group or mixtures thereof.

The above selective formulations results in the properties of controlled release of cefuroxime axetil. The present invention achieves a stabilized controlled release form even on storage in accelerated environment. These advantages of the selective and cost-effective formulation is clearly surprising and unexpected in the backdrop of the teachings of the cited prior art which does not in any manner whatsoever hint at the possibility of avoiding the problem of gelling and storage stability by a selective inner and outer coating over the active cefuroxime axetil. The surprising and special effect achieved by the composition is further demonstrated by the data shown in figure 1 which shows that a simple coating of Eudragit RS 30D or Eudragit RL 30D or Eudragit L 30D 55 does not and cannot achieve the desired controlled release. It is only the combination of two that achieves selective controlled release of the active. The

controlled release form of US Patent 5,580,578 does not propose any such combination for controlled release. WO 99/44614 on the other hand is not directed to any such controlled release form of cefuroxime axetil.

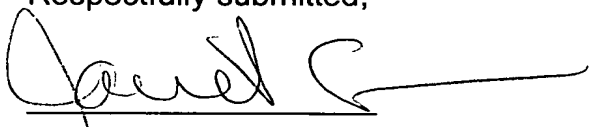
In view of the above, it is clear that the claimed invention is not obvious from the combination of the cited references and it is respectfully requested that the rejection be withdrawn.

The Examiner has rejected claims 2 and 23 as being obvious over the combination of cited prior art of WO 99/44614 and US 5,580,578 as applied to claims 1, 3-22 and 24-63, in view of US patent 4,325,960. Applicants respectfully traverse this rejection.

Since claims 1, 3-22 and 24-63 are not obvious over the combination of WO 99/44614 and US Patent 5,580,578, claims 2 and 23 which depend from claim 1 cannot be obvious in view of the combination of these references. Therefore, it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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